K111926

MAY - 1 2012

510 K SUMMARY

Submitted By:	Psychemedics Corporation 5832 Uplander Way Culver City, CA 90230 TEL: 310 216 7776 FAX: 310 216 6662
Submission Contact:	Virginia Hill
Date Prepared:	April 25, 2012
Device Trade Name:	Psychemedics Microplate EIA for Opiates in Hair
Predicate Device:	Psychemedics Opiates Assay, k000851
Product Code:	DJG
Device Classification/Name:	21 CFR 862.3650, Enzyme Immunoassay, Opiates; Classification II;
Intended Use:	The Psychemedics Microplate EIA for Opiates is an enzyme immunoassay (EIA) for the preliminary qualitative detection of opiates in human head and body hair using a morphine calibrator at 2 ng /10 mg hair cutoff for the purpose of identifying opiate use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The Psychemedics Microplate EIA opiate assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.
Assay Description:	The test consists of two parts; a **pre-analytical** hair treatment procedure (to convert the solid matrix of hair to a measurable liquid matrix) and the **screening assay**, the Psychemedics Microplate EIA for Opiates. The drug is recovered from the hair using a patented method (U.S. Patent #8,084,215).The screening portion of the test system consists of (1) microplate wells coated with multiple drugs including morphine conjugated to bovine serum albumin (BSA) (patent pending), polyclonal sheep anti-morphine, rabbit anti-goat secondary antibody conjugated to HRP (horseradish peroxidase), substrate [3, 3', 5, 5' tetramethylbenzidine (TMB)], HCl to acidify the final reaction, and wash buffer for washing the plates. Absorbance in the wells is read with a microplate reader.
Sample Collection:	A sample of hair should be cut as close as possible to the skin. The hair is placed in a V-shaped aluminum foil sample holder with the root end of the hair protruding beyond the slanted edge of the foil. The aluminum

foil is crimped around the sample, securing the hair specimen firmly into place within the foil. The hair samples crimped within the foil is placed in a sample acquisition card envelope and the envelope is sealed with a tamper-evident seal. Hair specimens are kept at ambient temperature in a secure location until they are shipped without refrigeration to the laboratory.

Materials required: Hair sample collection kit, Microplate EIA for Opiates, Microplate washer and reader, LC/MS/MS for confirmation.

Comparison of Psychemedics Microplate EIA for Opiates with Psychemedics RIA Assay for Opiates

Item	Device	Predicate
Indications for Use	The Psychemedics Microplate EIA for Opiates is an enzyme immunoassay (EIA) for the preliminary qualitative detection of opiates in human head and body hair using a morphine calibrator at 2 ng /10 mg hair cutoff for the purpose of identifying opiate use. This is an *in vitro* diagnostic device intended exclusively for Psychemedics use only and is not intended for sale to anyone. The test is not intended for over the counter sale to non-professionals. The Psychemedics Microplate EIA opiate assay provides only a preliminary analytical test result. A more specific alternative chemical method must be used in order to obtain a confirmed analytical result. Gas or Liquid Chromatography/Mass Spectrometry (GC/MS or LC/MS or LC/MS/MS) is the preferred confirmatory method. Clinical consideration and professional judgment should be exercised with any drug of abuse test result, particularly when the preliminary result is positive.	The Psychemedics Opiate assay is a radioimmunoassay (RIA) for the preliminary detection of morphine in hair using a 2 ng/10 mg hair cutoff for the purposes of identifying opiate use. For a quantitative analytical results or to confirm positive results *via* the presence of the heroin metabolite, 6-monoacetylmorphine (6-MAM), a more specific alternate chemical method must be used in order to obtain a confirmed analytical results
510k	K111926	K000851
Measurand	Opiates	Opiates
Matrix	Human head or body hair	Human head or body hair
Cutoff concentration	2 ng morphine10 mg hair	2 ng morphine /10 mg hair
Type of Test	Enzyme Immunoassay	Radioimmunoassay
Method of measurement	Microplate reader	Gamma counter
Extraction Method	Nonproteolytic Digestion	Proteolytic Digestion
Confirmation	LC/MS/MS	LC/MS/MS

Summary of Performance Testing

Precision Studies

Summary -Intra-Assay		
LEVEL	NEG	POS
B_0 (-100%)	15	0
-75%	15	0
-50%	15	0
-25%	15	0
plus 25%	0	15
plus 50%	0	15
plus 75%	0	15
plus 100%	0	15

Summary-Inter-Assay		
LEVEL	NEG	POS
B_0 (-100%)	75	0
-75%	75	0
-50%	75	0
-25%	75	0
plus 25%	0	75
plus 50%	0	75
plus 75%	0	75
plus 100%	0	75

Agreement Testing

The agreement studies included 383 head hair samples and 90 body hair samples. Four hundred-seventy-three hair samples were assayed by the predicate device and by the Psychemedics Opiates EIA. The discordance between EIA and RIA was < 0.2%.

	Negative by Predicate	**Positive by Predicate**
EIA Positive	0	156
EIA Negative	316	1

Two-hundred fifty-three of the samples were confirmed by LC/MS/MS, with the results shown in the following table.

LC/MS/MS:	**Negative**	**≥10% and < -50% of Cutoff**	**≥ -50% and < Cutoff**	**≥ Cutoff, and < +50% of cutoff**	**≥ +50% and < +100% of cutoff**	**≥ +100% of cutoff**
EIA Positive	0	0	8	9	8	126
EIA Negative	86	14	2	0	0	0

Samples vary in the amount of contamination on the surface; in fact, contamination is, by its very nature, random in the way in which it may present on the hair sample. Therefore, it is not surprising that a sample might be positive in one screening assay and not in the next, even if the assays are the same technology. The samples were negative by LC/MS/MS, demonstrating that the EIA negative results, although discordant with the predicate, are correct.

Cosmetic Treatments

Twenty opiate-negative hair samples were treated with bleach, 20 with permanent wave, 20 with dye, 20 with relaxer, and 20 with shampoo, and the results compared to the same samples without the treatments. In each case of the 20 samples treated with a type of cosmetic treatment, 10 samples were treated with one brand of a particular product and 10 other samples with a second brand. No significant differences were observed for the negative hair samples before and after the treatments; all samples remained negative after the treatments.

Twelve opiate-positive hair samples were treated with bleach, 12 with permanent wave, 12 with dye, 12 with relaxer, and 12 with shampoo, and the results compared to the same samples without the treatments. In each case of the 12 samples treated with a type of cosmetic treatment, 6 samples were treated with one brand of a particular product and 6 other samples with a second brand. The average of the EIA B/B_0 x 100 values obtained for the samples in each set before treatment is shown, with the range following in parenthesis. In the second row of the table, the average of the EIA B/B_0 x 100 values obtained for the samples in each set after treatment is shown, with the range following in parenthesis. No opiate-positive samples became negative after the cosmetic treatments.

Treatment Status	Bleach	Dye	Perm	Relaxer	Shampoo
	Mean (Range) of B/B_0 x 100 Values of 12 Opiate-Positive Samples in Opiate EIA				
Before	23.3 (13.5 – 37.5)	24.0 (13.5 – 46.9)	22.2 (10.6 – 48.7)	23.8 (13.8 – 37.9)	24.4 (13.8 – 48.7)
After	28.9 (16.8 – 46.4)	28.6 (14.2 – 48.7)	26.7 (12.9 – 52.0)	26.9 (12.1 – 42.7)	25.5 (14.0 – 43.7)

Summary of Contamination Study

Potential environmental contamination of samples that are identified as presumptive positive in the screening assay is addressed by an extensive washing procedure prior to confirmation and application of a wash criterion following confirmation, as described below.

Contamination of 8 hair samples by soaking in 1000 ng morphine /mL of water resulted in a range of morphine on the hair of 67.9 to 265.2 ng of morphine /10 mg hair before washing. After washing by the procedure described below, the amount of morphine remaining on the hair samples ranged from 0.8 to 3.4 ng/10 mg hair, with 5 samples appearing to be positive before application of the wash criterion. After application of the wash criterion (see below), all of these samples containing morphine above the cutoff were determined to be contaminated rather than positive and would not be reported as positive samples.

Contamination of 8 hair samples by soaking in 1000 ng morphine /mL of saline resulted in a range of morphine on the hair of 9.6 to 61.1 ng of morphine /10 mg hair before washing. After washing by the Psychemedics hair washing procedure described below, the amount of morphine remaining on the hair samples ranged from 0.3 to 1.3 ng/10 mg hair, with all samples negative (i.e., below the cutoff) even without application of the wash criterion.

The Wash Procedure

a. Wash by Psychemedics' standard wash procedure:
    i. Add 2 mL of dry isopropanol and shake in waterbath for 15 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove isopropanol.
    ii. Add 2 mL of Wash Buffer (0.01 M phosphate buffer, pH 6.0, containing 0.1% BSA) and shake in waterbath for 30 minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
    iii. Repeat Step ii. two more times.
    iv. Add 2 mL of Wash Buffer, and shake in waterbath for 60minutes at 37°C with shaking @ 100 -120 oscillations/minute. Remove Buffer.
    v. Repeat Step iv. one more time. Remove Buffer. Save Wash.
b. Analyze last wash for opiates.

Confirmation and Interpretation

a. Perform confirmation procedures for opiates.
b. Calculate wash criterion:

i. Multiply the last wash value x 5.
ii. Subtract the value of the parent drug in the last wash from the value of the parent drug in the digested hair.
iii. If the result is less than the cutoff for the parent drug, the sample is interpreted as contaminated. If the result is ≥ the parent drug cutoff, in combination with other metabolite criteria, the sample is interpreted as positive due to ingestion. The confirmation cutoff values for the opiates is 2 ng/10 mg hair.

Summary of Cross-reactivity and Interference Studies

Six compounds, shown in the table below, showed cross-reactivity in the Opiate EIA assay. Sixty-five other compounds showed no cross-reactivity in the assay. One-hundred-fifty-six compounds tested for interference at +/-50% of the cutoff showed no interference in the assay.

Cross-reactivity of related Compounds in Opiates EIA

Compound	Amount of Compound required to Produce a positive test at the cutoff of 2 ng morphine/10 mg hair	Percent Cross-reactivity*
Codeine	1.8	111
Hydromorphone	38	5.2
Hydrocodone	4.8	41.7
Acetylcodeine	3.5	57.1
6-Acetylmorphine	4.6	43.5
Morphine Glucuronide	13.3	15

Stability of Calibrator and Control Solutions

The morphine calibrator and control solutions are prepared in-house by the laboratory from certified standards. Stability of morphine in methanol in the presence of other drugs of abuse was shown to exceed 1 year.

Recovery

Recovery of opiates from hair of opiate users was shown to be substantially equivalent to that of the predicate device.

Conclusion:

The Psychemedics Microplate EIA for Opiates in Hair is substantially equivalent to the predicate device k000851, and the results are substantially equivalent to LC/MS/MS results.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration

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Silver Spring, MD 20993

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MAY - 1 2012

Re: k111926
Trade Name: PSYCHEMEDICS MICROPLATE EIA FOR OPIATES IN HAIR
Regulation Number: 21 CFR §862.3650
Regulation Name: Opiate Test System
Regulatory Class: Class II
Product Codes: DJG
Dated: March 9, 2012
Received: March 12, 2012

Dear Ms. Hill:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (301) 796-5760. For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance...

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-5680 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm

Sincerely yours,

Courtney H. Lias, Ph.D.
Director
Division of Chemistry and Toxicology Devices
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indication for Use

510(k) Number: k111926

Device Name: Psychemedics Microplate EIA for Opiates in Hair

Indications For Use:

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Prescription Use _____ (21 CFR Part 801 Subpart D)

And/Or

Over the Counter Use __X__ (21 CFR Part 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE; CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Device Evaluation and Safety (OIVD)

Division Sign-Off
Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) k111926